

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2561 Rayburn House Office Building
Washington, DC 20515-6515

June 28, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Califf,

The House Committee on Small Business (Committee) writes to inquire about the recent proposed rule to create a product standard for cigars that would result in a product ban of all cigars with a “characterizing flavor” other than tobacco.¹ The Committee has followed the Food and Drug Administration’s (FDA) process as it relates to this rulemaking and seeks to further understand FDA’s consideration of the economic impacts on small entities that would result from implementation of this proposed rule.

Small businesses make up 99.9 percent of all businesses in the United States. This is why the Regulatory Flexibility Act (RFA) requires regulatory agencies to consider the impact of their rules on small businesses, and to evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities. We have reviewed the FDA’s May 2022 Preliminary Regulatory Impact Analysis and identified several unanswered questions which we believe should have been considered when assessing the economic impact of the proposed rule.² As such, we request answers to the following on or before July 12, 2023:

1. The analysis indicates that more than 115,000 small business retailers of flavored tobacco products will be impacted by the proposed rule.³ Please quantify the revenue loss that banning the products under the proposed rule would have on average small business retailers by category (such as convenience stores, grocery stores, pharmacies, tobacconists, etc.).
2. Given the revenue loss referenced in question 1, how many small businesses do you estimate will be forced to close because of the proposed rule?

¹ 87 Fed.Reg. 26396 (May 4, 2022).

² DEP’T OF HEALTH & HUMAN SERV., FOOD & DRUG ADMIN., FDA-2021-N-1309, TOBACCO PRODUCT STANDARD FOR CHARACTERIZING FLAVORS IN CIGARS (May 2022).

³ *Id.* at 109.

- a. What is your estimate on reduced employment figures associated with these small business closures?
 - b. What is your estimate on reduced employment figures for businesses that remain open but with reduced revenues?
3. Given that many of the small businesses projected to be impacted by the rule are sources of food and pharmaceuticals in local communities, what data can the FDA share about the effect that the proposed rule will have on “food deserts” and “pharmacy deserts”?
4. The preliminary analysis only details one alternative — a delayed effective date — to minimize the proposed rule’s burden on small businesses.⁴ What other alternatives has the FDA considered or analyzed?
5. Given the FDA’s expressed interest in the proposed rule’s impact on minority communities, what data can the FDA share regarding the effect on minority-owned small businesses? Please include data related to the impact on revenue, employment, and viability for these businesses.

To schedule the delivery of your response or ask any related follow-up questions, please contact Committee on Small Business Majority Staff at (202) 225-5821. The Committee on Small Business has broad authority to investigate “problems of all types of small business” under House Rule X. Thank you in advance for your cooperation with this inquiry.”

Sincerely,



Roger Williams
Chairman
Committee on Small Business



Dan Meuser
Member
Committee on Small Business

cc: The Honorable Nydia M. Velasquez, Ranking Member
Committee on Small Business

⁴ *Id.* at 112.